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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE APPLICATION NO. 11/13/2003 Richard B. Nappi 1579-823 5655 10/706,269 **EXAMINER** 23117 7590 12/28/2005 NIXON & VANDERHYE, PC CHIEM, DINH D 901 NORTH GLEBE ROAD, 11TH FLOOR ART UNIT PAPER NUMBER ARLINGTON, VA 22203 2883

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/706,269	NAPPI ET AL.
	Examiner	Art Unit
	Erin D. Chiem	2883
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		•
 Responsive to communication(s) filed on 12 October 2005 and 13 October 2005. This action is FINAL. This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. 		
Disposition of Claims		
4) ☐ Claim(s) 1-3 and 5-21 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-3 and 5-21 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement.		
Application Papers		
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on 13 November 2003 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage		
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/88) Paper No(s)/Mail Date U.S. Patent and Trademark Office PTOL 326 (Pox 7 05) Pager No (s) (Pox 7 05)		
PTOL-326 (Rev. 7-05) Brian Healy Office Ad	ction Summary Pa	art of Paper No./Mail Date 20051221

DETAILED ACTION

This office action is in response to the amendment filed on October 12, 2005 and October 13, 2005. In the amendment filed on October 12, 2005, claims 1 and 5 are substantially amendment while in the amendment filed on October 13, 2005 the dependency to claims 6-8, 10, 17, and 19 were amended.

The examiner acknowledges the telephonic conference with Supervisory Examiner Font on October 12, 2005 and agrees with the regrouping of claim 25 with the non-elected invention of claims 26-30.

In view of the amendment and remarks, objection made to claim 8 is withdrawn and the rejection to claim 7 made under 35 USC 112 is also withdrawn.

Currently, claims 1-3, and 5-21 are pending.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the comparison between the increased light-diffusion profile versus a comparable fiber having no light diffusing particles light-diffusion profile must be shown or the feature(s) canceled from the claim(s). Since applicant claims that the present invention provides an unexpected result of the light diffusion profile in the optical fiber illuminator with light diffusing medium versus a regular optical fiber, the examiner finds that this limitation is important to the present invention and therefore the limitation must be shown in the drawings. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

objection to the drawings will not be held in abeyance.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-6 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Sinofsky et al. (US 6,071,302 hereinafter "Sinofsky").

Regarding claims 1-6 and 21, Figure 1 shows an optical fiber illuminator comprising an optical fiber 12 and light diffusing medium 24 affixed to a terminal end of the optical fiber. Sinofsky uses MastersilTM formula 151-Clear as the light-diffusing medium (datasheet is included for applicant's review) and formula 151 is a bonding material shaped for affixing the light-diffusing particles to the terminal end of the optical fiber (col. 5, line 50-60). As an alternative, Sinofsky also teaches using silica or alumina as diffusing particles (col. 5, lines 57) mixed with water or deuterium oxide solution and both have a refractive index of 1. In the present prior art, silica (SiO₂) and alumina (AL₂O₃) are terms used in the art as compounds that primarily comprises of silica and alumina with other additives such that the compound would transmit light. Note Table 1 teaches the transmission spectrum of the three compounds. From Fig. 1 and Fig. 3, Sinofsky shows two embodiments of the particles, one having regular symmetrical spherical geometry (Fig. 1) and another embodiment having irregular geometry (asymmetrical) (Fig. 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sinofsky. Sinofsky discloses an illuminator comprising an optical fiber having a light diffusing medium affixed to the terminal end of the fiber wherein the medium is a bonding material comprising

solid light diffusing particles dispersed in the bonding material; except, Sinofsky does not disclose the amount of particles representative in percentage by volume.

On page 9, line 5-18, Applicant teach that the result effective variable of light diffusion profile is modifiable by adjusting the amount of light-diffusing particles 20 that are dispersed in the bonding material.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to experimentally vary the concentration of the particles by volume to achieve the desired light diffusion profile, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

<u>Claims 11-16</u> are rejected under 35 U.S.C. 103(a) as being unpatentable over Sinofsky in view of Bruce (US 5,534,000).

Sinofsky teaches an illuminator comprising an optical fiber having a light diffusing medium affixed to the terminal end of the fiber wherein the medium is a bonding material comprising solid light diffusing particles dispersed in the bonding material. However, Sinofsky does not explicitly teach the particle size in the medium having an average particle diameter between 5.0 microns to 10.0 microns. (NOTE: the range 5.0 – 10.0 microns reads on the ranges of claims 11-14)

Bruce teaches an illuminator comprising a fiber 14 and a diffusing tip comprising a bonding medium having diffusing particles dispersed in the bonding medium 18. Bruce teaches in detail the particle diameter being 3 microns in size (col. 5, line 46) and the particle diameter is

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substantially less than one-fourth the diameter of the optical fiber 12 having 1000 microns (col. 5, line 33).

Since Sinofsky and Bruce are both from the same field of endeavor, the purpose disclosed by Bruce would have been recognized in the pertinent art of Sinofsky.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to a bonding material having such small sized particles for the purpose effectively diffusing light in the wavelength range of 0.2-9 microns. The motivation for using bonding material having such small sized particles is such that the material can be placed into a syringe and deposit into the Teflon tube at the distal tip of the fiber (col. 5, line 47-60).

Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sinofsky in view of Intintoli et al. (US 6,893,432 B2 hereinafter Intintoli).

Sinofsky teaches an illuminator comprising an optical fiber having a light diffusing medium affixed to the terminal end of the fiber wherein the medium is a bonding material comprising solid light diffusing particles dispersed in the bonding material. However, Sinofsky does not explicitly teach the difference between the refractive indices is less than 5% nor does Sinofsky teach the Fresnel reflection at the interface between the bonding material and optical fiber is less than 1%.

Intintoli teach the refractive index difference between the particle and the fiber core is less than 5% (col. 10, line 48-49) for the purpose of promoting further internal reflection.

Since Sinofsky and Intintoli are both from the same field of endeavor, the purpose disclosed by Intintoli would have been recognized in the pertinent art of Sinofsky.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to choose two optical transmitting material having similar refractive indices such that the difference between the indices is minimal. **The motivation** for choosing optical transmitting materials having similar refractive indices is for promoting further internal reflection (Intintoli col. 10, line 33-34).

Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sinofsky. Sinofsky teaches an illuminator having a diffusing tip comprising bonding material with dispersive particles. The bonding material must have a greater refractive index than the housing wall or fiber. Furthermore Sinofsky teaches the critical angle for internal reflection for the interface (col. 4, line 44-56). However, Sinofsky does not explicitly teach the Fresnel reflection at the interface between the bonding material and the optical fiber is less than about 5% to less than about 1%. It would have been obvious to one having ordinary skill in the art at the time the invention was made to select the two optics transmitting material (i.e., for the optical fiber and the diffusing particles within the bonding material) to have low refractive indices difference to further cause light to reflect internally; since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed on October 12, 2005 have been fully considered but they are not persuasive.

Regarding applicant's argument that Sinofsky teaches oxides of titanium, silicone, and aluminum is partially correct. The specific oxide of titanium taught is titanium dioxide (TiO₂),

more commonly known as titania. Sinofsky does not teach aluminum, instead, Sinofsky teaches aluminum dioxide (Al_2O_3), commonly known as alumina. On the contrary with applicant drawing similarity between silicone and silica in the remark on page 9, second paragraph – silicone (i.e., silica (SiO_2))--. Although the language distinction is minor but the chemical make up of these compounds are physically and chemically different (i.e., silica is mineral-like compound and silicone is a compound with a polymeric backbone).

Firstly, note that these compounds disclose by Sinofsky is taught to one having ordinary skill in the art to state that the compound primarily consists of the named compound. For example, it is well known in the art that alumina in its purest form is opaque but in the optics art it is common to use magnesium as an additive to change the light transmission property of alumina. Applicant pointed this out in the http://navier.engr.colostate.edu/whatische/CheEl05Body.html reference, but fails to disclose the

sentence that follows which states —However, when very small amount of magnesium (Mg) are added to the system during processing, the not-quite-pure alumina film becomes optically translucent—. The practice of adding magnesium to alumina was known before 1970, for applicant's review please see Frock's patent on reversible record and storage medium (US Patent 3,704,467). Regarding the reference

http://mineral.galleries.com/minerals/elements/silicon/silicon.htm, this reference teaches the properties of silicon, a chemical element Si and not the chemical compound SiO₂. And silica is well known to have transparent properties.

Secondly, MasterBond[™] Sinofsky discloses that the silicone (n=1.41) is clear in the Mastersil[™] formula 151 and this formula has been successfully manufactured, marketed, and used in various applications.

Thirdly, applicant teaches that the transparent particles may be optically transparent silica (Specification Page 7, lines 16-17). Applicant's remark contradicts with the disclosure in the Specification.

In summary, applicant's arguments regarding the compounds taught by Sinofsky, Bruce, and Intintoli are not opaque is not persuasive. Sinofsky unambiguously states in Table 1 that the compounds have transmission spectra at specific wavelength ranges. Furthermore, Sinofsky teaches the common optical diffusion compound, Mastersil TM 151, used in the art for diffusion purpose and also teaches alternative compounds to use in place of MastersilTM 151. And finally, applicant's remark is contradictory to the Specification. The points made above leads the examiner to disagree with the "opaque" argument, thus the examiner asserts the rejection made in the prior office action with mail date July 13, 2005.

Finally, the examiner would like to emphasize that although Sinofsky's reference is referred to as a phototherapeutic diffusion apparatus, but the phototherapeutic application that Sinofsky's apparatus was intended to uniformly illuminate a large region of tissue. Furthermore, highly intensified and focused light beam is undesired in Sinofsky's application because highly intensified and focused light beam creates hot spots in the illuminated tissue which leads to tissue damage, please see column 1 lines 51-63. Thus a diffusive tip apparatus that delivers omnidirection illumination field to a "phototherapy site" is the motivation for Sinofsky's apparatus.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erin D. Chiem whose telephone number is (571) 272-3102. The examiner can normally be reached on Monday - Thursday 9AM - 5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frank G. Font can be reached on (571) 272-2415. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Erin D Chiem Examiner Art Unit 2883

> Brian Healy Primary Exeminer